UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.*, DANIEL C. RICHARDSON, Plaintiffs, vs. BRISTOL-MYERS SQUIBB, Defendant.	Docket No. 06-11821-NG The Hon. Nancy Gertner **FILED UNDER SEAL** FIRST AMENDED COMPLAINT FOR VIOLATIONS OF: FEDERAL FALSE CLAIMS ACT [31 U.S.C.§3729 et seq.]; ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT [Ark. Code Ann. § 20-77-901 et seq.] CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. Code Ann. §1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 et seq.]; GEORGIA STATE FALSE MEDICAID CLAIMS ACT [Ga. Stat. § 49-4-168 et seq.] HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 et seq.]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. Ann. §175 et seq.]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION [Ind. Code § 5-11-5.5-1 et seq.]

LOUISIANA FALSE CLAIMS ACT [La. Rev. Stat. Ann. § 46:437.1 et seq.]

MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws, Ch.12, §5 et seq];

MICHIGAN MEDICAID FALSE CLAIMS ACT [11 MCL § 400.611 et seq. (Mich. Public Act 337 (2005))]

MONTANA FALSE CLAIMS ACT [Mont. Code Ann. § 17-8-401 et seq. (2005 Mont. Code, Ch. 465, HB 146)]

NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.];

NEW HAMPSHIRE MEDICAID FRAUD AND FALSE CLAIMS ACT [NH Code § 167:61-b et seq.]

NEW JERSEY FALSE CLAIMS ACT [Supplementing Title 2A of the New Jersey Statutes and amending 2 P.L. 1968, c. 413 (N.J.S.A. 2A:32C-1), signed by Governor April 15, 2008]

NEW MEXICO MEDICAID FALSE CLAIMS ACT AND FRAUD AGAINST TAXPAYERS ACT [N.M. Code § 27-14-1 et seq. and § 44-9-1 et seq.]

NEW YORK FALSE CLAIMS ACT [McKinney's New York State Finance Law § 187 et seq.]

OKLAHOMA MEDICAID FALSE CLAIMS ACT [Okla. Code, Title 63, § 5053 et seq.]

RHODE ISLAND FALSE CLAIMS ACT [§ 9-1.1-1 et seq.]

TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §71-5-181

et seq.];

TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. §36.001 et seq.];

UTAH FALSE CLAIMS ACT [Utah Stats. § 8.01-216.1 et seq.]

VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann. §8.01-216.1 et seq.];

WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT [Wis. Stats. § 20.931 et seq.]

DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Stat. §2-308.14, formerly D.C. Code Ann. §1-1188.13 et seq.]

JURY TRIAL DEMANDED

Plaintiff-Relator, Daniel C. Richardson, by and through counsel, hereby submits this First Amended Complaint ("FAC") on behalf of the United States of America, the State of Arkansas, the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Utah, the Commonwealth of Virginia, the State of Wisconsin, and the District of Columbia (collectively "the States and the District of Columbia"). The FAC against Defendant Bristol-Myers Squibb Co. ("BMS") is based upon personal knowledge, relevant documents, and

information and belief.

I. PRELIMINARY STATEMENT

This is a *qui tam* action under 31 U.S.C. Sec. 3729, *et al.* of the False Claims Act filed by Relator/Plaintiff Daniel C. Richardson, in the name of the United States Government and himself, to recover penalties and damages arising from Defendants' violations of federal requirements concerning the marketing, promotion and sale of pharmaceuticals purchased through Medicaid, Medicare and other government programs.

On May 4, 2006, Mr. Richardson filed his Complaint under seal on behalf of the United States, in the U.S. District Court for the District of Columbia, whereby he alleged that the Defendants' illegal kickbacks, marketing and off-label promotion of numerous drugs and products caused the submission of many false claims to the United States in violation of the federal False Claims Act ("FCA"). Subsequently, Mr. Richardson's Complaint was transferred to the District of Massachusetts at the request of the United States of America, where this action remained under seal pursuant to the False Claims Act.

In September of 2007, the United States of America and the Defendant agreed to settle some of the claims alleged by Mr. Richardson and pursuant to a settlement agreement between the United States, Mr. Richardson and BMS, a portion of Mr. Richardson's claims were settled and dismissed with prejudice. This Court entered an Order of Dismissal dated October 23, 2007 [Doc. #22-2], which provided that: Consistent with the terms of the Settlement Agreement executed by the United States, BMS, and the relator, (a) all claims asserted on behalf of the United States in Civil Action No. 06-11821-NG concerning the Covered Conduct as defined in Preamble Paragraph N(3) of the Settlement Agreement shall be dismissed with prejudice, and (b) except for those claims alleged in Paragraphs 90-94, 97-103, 105, and 112-115 of Section II of

the Complaint filed on or about May 4, 2006, all remaining claims asserted on behalf of the United States against BMS and any claims against Sanofi-Aventis or GlaxoSmithKline based on BMS's conduct are dismissed with prejudice as to the Relator and without prejudice as to the United States. Order, p. 1. In addition, the Court's Order of Dismissal provided that "All other claims alleged against Sanofi-Aventis and/or GlaxoSmithKline based on their own conduct, and not based on BMS's conduct, are not dismissed at this time," and that "[n]o claim or allegation other than those as specifically identified in the stipulation and herein shall be dismissed at this time." *Id.*, p. 2.

The Court's Order of Dismissal further stated that as "to dismissed claims and allegations, the Court shall retain jurisdiction to decide issues concerning Relator's expenses, attorneys' fees, and costs under 31 U.S.C. §3730(d)." *Id.* Additionally, dismissal was without prejudice as to relator's claims for expenses, attorney's fees and costs and BMS's right to challenge or seek dismissal of relator's claims for expenses, attorney's fees and costs. *Id.*

This action remained under seal while the United States conducted further investigation of the claims alleged by Mr. Richardson that were not settled. On December 11, 2008, the Department of Justice filed its notice of declination of intervention on Mr. Richardson's remaining claims, and for the first time, allowed Mr. Richardson to proceed to litigate this action without government intervention.

This First Amended Complaint restates those claims against BMS under the Federal False Claims Act that were not specifically identified and settled in the parties' settlement agreement. In addition, this First Amended Complaint alleges claims against BMS pursuant to various state False Claims Act laws for conduct that was not settled or dismissed.

JURISDICTION AND VENUE

1. Plaintiff, Daniel C. Richardson, hereby alleges causes of action under 31 U.S.C. § 3729, *et seq.*, of the False Claims Act, arising from Defendant's conduct in the marketing, promotion and sale of pharmaceuticals purchased through the Medicaid and Medicare programs and other government programs.

2. Plaintiff is the original source of all the allegations contained in this Amended Complaint.

3. There has been no public disclosure of the allegations contained in this Amended Complaint.

4. Pursuant to the requirements of the False Claims Act 31 U.S.C. § 3729, *et seq.*, the plaintiff has provided the government with a confidential disclosure statement and exhibits to substantiate his allegations.

5. Jurisdiction over all stated causes of action is conferred upon this Court by 31 U.S.C. § 3732, and 28 U.S.C. §§ 1331 and 1367, in that this action arises under the laws of the United States. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendant has minimum contacts with the United States. Moreover, the Defendant can be found in, resides, or transacts or has transacted business in the District of Massachusetts.

6. The Defendant is in the business of selling pharmaceuticals to patients through the federally funded Medicaid and Medicare and government programs, the Defendant conducts business in Massachusetts, and made significant sales within Massachusetts and some of the alleged False Claims Act violations occurred in Massachusetts.

7. Venue and jurisdiction are proper in this District pursuant to 28 U.S.C. § 1391(c) and 31

U.S.C. § 3732, because the Defendant can be found in and transacts or has transacted business in the District of Massachusetts. At all times relevant to this Complaint, Defendant regularly conducted substantial business within the District of Massachusetts, maintained employees and offices in Massachusetts, and made significant sales within Massachusetts. In addition, the statutory violations, as alleged herein, occurred in this district.

THE PARTIES INVOLVED

8. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

9. Plaintiff-Relator, Daniel C. Richardson, is a Senior District Business Manager for Bristol-Myers Squibb ("BMS"). During a portion of the times relevant to this Complaint, Mr. Richardson's BMS Business District included Washington, D.C., Florida, Georgia, Maryland and Virginia. Mr. Richardson has worked for BMS for more than 20 years and resides at 1007 Romancoke Road, Stevensville, MD 21666.

10. Defendant Bristol-Myers Squibb ("BMS"), a Delaware Corporation, is a pharmaceutical company headquartered at 345 Park Avenue, New York, NY 10154. BMS is principally engaged in the manufacture and sale of pharmaceuticals and has global sales of approximately $19.2 billion. BMS has and continues to conduct business in the District of Massachusetts, and nationwide.

BACKGROUND AND APPLICABLE LAW

11. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

A. The FDA Regulatory Scheme

12. The Food Drug and Cosmetic Act prohibits Defendant BMS from marketing or promoting approved drugs for uses other than those set forth in the drugs' approved labeling. This regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body. Defendant BMS engaged in a course of unlawful conduct to promote off-label uses of its approved drug Pravachol. For example, Pravachol, approved for reducing cholesterol and cardiac events, was promoted for other "off-label" uses such as acting as an anti-thrombotic agent, decreasing CD-40 ligand, decreasing matrix metalloproteinases, decreasing hsCRP levels and other mechanisms for "plaque stabilization" not included in the FDA-approved label.

13. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

14. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use for which the drug may be prescribed is called the "indication." The FDA will specify particular dosages determined to be safe and effective for each indication.

15. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§352, 355(d). An example of

the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

16. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those required for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, or treating the indicated condition at a different dose or frequency than specified in the label.

17. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

18. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws: (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose; and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which

includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331 and 352.

19. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

20. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products; and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses.

21. With regard to the first practice - disseminating written information - the FDAMA permits a manufacturer to disseminate information regarding off-label usage in response to an "*unsolicited request* from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1. The FDA has promulgated regulations to regulate the dissemination of off-label information by drug manufacturers. 21 C.F.R. Part 99.

22. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* The promotion of off-label drug uses at a CME program which is not "free from the supporting company's influence and bias" violates Congress' off-label marketing restrictions.

23. Promotional claims recommending or suggesting a drug for a use other than that for which FDA has reviewed safety and effectiveness data create a new "intended use" for which adequate directions must be provided in product labeling. 21 U.S.C. §352(f)(1); 21 CFR 201.5, 201.100, 201.128. Absent such directions, the drug is misbranded under Section 502(f)(1) of the misbranding statute. 21 U.S.C. § 352(f)(1).

24. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, i.e., the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

25. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription will be reimbursed under Medicaid and other federal or state health care programs.

26. Drugs not approved for such uses, including Pravachol, are not subject to reimbursement by Medicaid or by state health care programs at the time of the Defendant's promotional

campaign, including without limitation those states on whose behalf Mr. Richardson has asserted causes of action.

27. During the time period of Defendant's promotional campaign, off-label claims for reimbursement for Pravachol from Medicaid or other federal or state insurers would, therefore, have constituted false claims.

28. Additionally, during the time period of Defendant's promotional campaign, off-label claims for reimbursement based on the promotion of mechanisms of actions of Pravachol that are not consistent with the approved product labeling is misleading and such claims for reimbursement based on off-label promotion of Pravachol would also have constituted false claims.

1. The Medicaid Program

29. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

30. At all material times, BMS participated in the Medicaid Drug Rebate Program, 42 U.S.C. §1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Drug Rebate Program, BMS entered into a rebate agreement with the Health Care Financing Administration ("HCFA"), now known as the Centers for Medicare and Medicaid Services ("CMS"), and BMS's drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10(A), 1396d(a)(12), and 1396r-8(a)(1).

31. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* §1396r-8(k)(3). They do not include drugs use for a medical indication, which is not a medically accepted one. *Id.*

32. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or which is included in one of the drug compendia identified in the Medicaid statute. Id. §1396r-8(k)(6). During the time period relevant to this Complaint, the off-label uses of Pravachol promoted by Defendant BMS were not eligible for reimbursement as medically accepted indications.

2. Other Federal and State Health Care Programs

33. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

34. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United

States Office of personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, e.g.,TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

35. During the time period relevant to this Complaint, the off-label uses of Pravachol promoted by BMS did not qualify for reimbursement under any of the various federal and state health care programs.

3. The Anti-Kickback Statute

36. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

37. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by Medicaid,

CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, or other federal health care program.

38. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company to a physician, which has as one of its purposes inducement of the physician to write additional prescriptions for the company's pharmaceutical products.

39. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the improper practices cited by the Inspector General are drug companies' payments to physicians where the physician had offered no particular services of benefit to the drug company but the payment appeared to have been based on the volume of business the doctor could generate for the drug company. *Id.*

40. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In a number of states, the Medicaid claim

form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

41. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law, the ban on off-label promotion and law against misbranding.

42. As described more fully below, Defendant BMS, between 1998 through at least 2003, and probably thereafter, knowingly and intentionally violated the regulatory schemes in the marketing and sales of Pravachol. When Defendant BMS intentionally decided to employ these improper marketing and sales practices to promote its products, it knew or should have known, and BMS intended, that pharmacists, health care providers and physicians would routinely and necessarily file false claims with the federal government and state governments when seeking reimbursement for prescriptions of pharmaceutical products.

43. Plaintiff-Relator alleges that BMS knowingly and deliberately caused to be submitted false claims for payment for Pravachol to the Medicaid Program, the Medicare Program, established pursuant to Title XVIII of the Social Security Act, §§ 1395-1395hhh, the TRICARE Program (formerly known as the Civilian Heath and Medical Program of the Uniformed Services), 10 U.S.C. §§ 1071-1106, and the Federal Employees Health Benefit Program ("FEHBP"), 5 U.S.C. §§ 8901-14; and that BMS knowingly and deliberately caused the Department of Veterans Affairs ("DVA") and the U.S. Department of Defense ("DOD") to pay false claims for the purchase of Pravachol.

44. Additionally, Plaintiff-Relator alleges that BMS knowingly and deliberately caused to be submitted false claims for payment for Pravachol to the various States named herein.

FACTS

I. IMPROPER TRACKING AND TACTICS TO BOOST SALES AND INDUCE PRESCRIPTIONS

45. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

46. A Clinical Advisory Council ("CAC") is an event where a group of doctors listened to a BMS Medical Science Manager ("MSM") or paid physician speaker deliver a targeted sales presentation. Defendant BMS paid these doctors to listen to such a speech. Although the official purpose of the CAC's was to solicit feedback on market conditions, and the CAC's technically fell under BMS' category of "Medical Education," the CAC's were knowingly and deliberately misused by BMS to improperly and illegally drive prescription volume.

47. Between the years 2000 and 2003, each BMS sales district had a panel of 50 physicians who were paid honoraria to ostensibly provide consulting services. These panels of 50 physicians were called District Consultant-50 or DC-50. Prior to 2000, these panels were also known as District Advisory Boards ("DAB"), DC-25 and DC-30. As of March 22, 2002, BMS estimated the total number of maximum physicians employed as consultants in the DC-50 program nationwide at 15,300 physicians. These doctors were required to participate in at least three events, including CACs, Interactive Training Sessions ("ITS") and Preceptorships.

48. Local Clinical Advisory Councils ("LCAC") were CAC programs that invited doctors who were not members or consultants as part of a District Advisory Board or DC-50.

LCAC programs were launched to drive the sales of Plavix prescriptions and differed from typical CACs in that audience members were physicians brought in as consultants for the LCAC meeting specifically, signing a one-time only consultant agreement. In the Fall of 2001, Defendant BMS launched a "National CMRS Plavix LCAC Maximization Plan" to aggressively pursue an increase of new prescriptions of Plavix to 70% market share by the end of December 2001. One of the main objectives of Defendant BMS's Plavix LCAC "Maximization Plan" was to "increase Cardiology advocacy to drive" Primary Care Provider "prescribing habits." Defendant BMS's strategies in using the Plavix LCACs was to focus the Plavix message to the "Top Plavix prescribers" in order to lengthen the term of treatment by continuing to prescribe Plavix and to "leverage" the "sphere of influence" of top Plavix supporters with fellow Cardiologists and Primary Care Providers to increase sales of Plavix.

49. The physicians who were invited to these LCACs in 2002 were targeted as key influencers in the local market who were highly selected to influence the local medical community "to help drive Plavix business post-launch!"

50. After the DHHS Inspector General issued its guidance in 2003, BMS discontinued its use of DC-50s and preceptorships.

51. CAC's usually consisted of 8-14 doctors and BMS Marketing usually dictated the payment, material, and scope of the meetings. However, Defendant BMS paid speakers often used their own slide decks for the medical presentations and provided information to CAC attendees about off-label information for BMS products.

52. As an incentive to attend these meetings, Defendant BMS distributed honoraria to all participating doctors, generally about $250.

53. Notably, Defendant BMS specifically included CACs and preceptorships as resources to accelerate the growth of sales of BMS products for Medicaid patients. Once again, Defendant BMS targeted its top 50 Medicaid prescribers by district, by product and geographic area or ("POD"), focused attention to the top prescribers, and identified Medical Directors and physicians associated with Community Health Centers ("CHC") to support BMS sales efforts.

54. BMS Representatives were required to later track the prescribing habits of attending doctors and to evaluate the impact of the various CAC programs. Contrary to BMS policy and federal law, BMS Representatives tracked conference attendees' prescription habits to ensure an increase in BMS prescriptions. As one Field Contact Report made clear, CACs were exploited by BMS to "maximiz[e] the impact of" CACs by following up with and "driving the commitments from" physicians to prescribe BMS products after they had attended CACs.

55. Defendant BMS's Pravachol Marketing also provided payments to doctors covering honoraria and travel expenses. The local representatives were given money to create programs specifically targeted to their physicians. CACs were also used to promote and sell Pravachol.

56. These CACs and consultants' meetings were not held for the purpose of providing Defendant BMS with expert, independent advice. Defendant BMS in many cases did not even record the "advice" provided by its "consultants" and what advice was collected was never acted upon or reviewed. Indeed, no legitimate business would need hundreds or thousands of "consultants" to advise it on the same topic.

57 Defendant BMS tracked the new prescription market share of Pravachol for doctors who attended any of the following events in 2002: National ("Fly-To") Consultant Conferences, Regional ("Drive-To") Consultant Conferences, Regional CMEs, and CACs. Significantly, the results of BMS Marketing tracking of physician attendees at these events noted a marked increase in new prescriptions for doctors who attended as compared with doctors who were targeted but did not attend any events, and an even more dramatic increase was noted when attendees were subjected to follow up tactics.

58. During the period from January 1999 through December 2003, BMS knowingly and willfully offered and paid illegal renumeration to physicians, and to some physician assistants and nurse practitioners, through consulting fees and expenses for participating in National Consulting Conferences, Regional Consulting Conferences, Clinical Advisory Councils, District Advisory Boards, Interactive Training Sessions, Preceptorships, and similar consulting programs, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). During this time period, BMS also knowingly and deliberately caused the submission of false and/or fraudulent claims to Medicaid, Medicare, other federal health care programs, and caused DVA and the DOD to purchase BMS drugs, by inducing these physicians, physician assistants, and nurse practitioners to prescribe and/or to recommend the prescribing BMS drugs.

II. OFF-LABEL PROMOTION AND MISBRANDING

A. Overview of Off-Label Promotion and Misbranding of Pravachol

59. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.